OCT 2 0 2000

K002483

510 (k) Summary of Safety and Effectiveness

Submitter: Biomet Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Tracy Bickel

Product Code: 87 HWC

Device Name: LactoSorb® Push Screw

Indications: The LactoSorb® Push Screw is indicated for use in the following midface and craniofacial procedures.

A. General Indication: trauma procedures of the midface or craniofacial skeleton

Specific Indications:
1. Comminuted fractures of the naso-ethmoidal infraorbital areas
2. Comminuted fractures of the frontal sinus wall
3. Pediatric midface or craniofacial trauma
4. LeFort (I, II, III) fractures
5. Orbital floor fractures
6. Fractures of the maxilla, zygoma, zygomatic arch, orbital rim, nasal, ethmoid, and lacrimal bones
7. Trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones

B. General Indication: reconstructive procedures of the midface or craniofacial skeleton

Specific Indications:
1. Infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma, etc.,
2. LeFort (I, II, III) osteotomies
3. Tumor reconstruction in midface or craniofacial procedures
4. Bone graft procedures in the midface or craniofacial skeleton
5. Pediatric reconstructive procedures
6. Reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones
7. Craniotomy flap fixation

This system is not designed for use in the mandible and/or full load bearing procedures.

Device Description: The device is a screw having a non-threaded pin portion and a head portion. The pin portion having a diameter and 3 flat sides. The diameter has increasingly larger steps, acting as barbs to retain fixation in the bone.

The LactoSorb® 1.5 x 5mm Push Screw will be used in conjunction with the LactoSorb® Trauma Plating System (K971870) which consists of microplates, rivets, and screws used

in midface and craniofacial skeleton for reconstructive procedures. The Push Screw utilizes the same auxiliary break-off hex head and instrumentation as the standard LactoSorb® screws.

After the LactoSorb® Plates are shaped to the desired anatomy, the Push Screws are then inserted into the predrilled hole. The insertion of the screw does not require rotational movement, rather direct insertion into the hole. The push screw head geometry mates with the standard bone plate ensuring the same fit as a standard rotational screw.

Substantially Equivalent:

The LactoSorb® Push Screw is substantially equivalent to the LactoSorb® 1.5mm Screw (K971870) manufactured by Biomet, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2000

Ms. Tracy J. Bickel
Regulatory Specialist
Biomet, Incorporated
56 East Bell Drive
Warsaw, Indiana 46582

Re: K002423
Trade Name: LactoSorb® Push Screw
Regulatory Class: II
Product Code: DZL
Dated: August 4, 2000
Received: August 8, 2000

Dear Ms. Bickel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K002423

DEVICE NAME: LactoSorb® Push Screw

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002423

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)